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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/830,994      | 05/03/2001  | Kristiina Ylihonko   | 1574/49884          | 7174             |

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| EXAMINER |
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KERR, KATHLEEN M

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| ART UNIT | PAPER NUMBER |
|----------|--------------|

1652

DATE MAILED: 06/12/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                             |                  |
|------------------------------|-----------------------------|------------------|
| <b>Office Action Summary</b> | Application No.             | Applicant(s)     |
|                              | 09/830,994                  | YLIHONKO ET AL.  |
|                              | Examiner<br>Kathleen M Kerr | Art Unit<br>1652 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 14 August 2001.

2a) This action is **FINAL**.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-5 and 9-15 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) \_\_\_\_\_ is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) 1-5 and 9-15 are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some \* c) None of:

- Certified copies of the priority documents have been received.
- Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
- Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)  The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.

4) Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_.

5) Notice of Informal Patent Application (PTO-152)

6) Other: \_\_\_\_\_.

## DETAILED ACTION

### *Application Status*

1. By virtue of a preliminary amendment filed on May 3, 2001, which cancelled Claims 6-8 and added new Claims 14-15, Claims 1-5 and 9-15 are pending in the instant application.

### *Claim Interpretation for Purposes of Restriction*

2. The following is an interpretation of the pending claims, where necessary, that has led to the below restriction. Should this interpretation be argued by Applicants to be in error, a supplemental restriction requirement may be necessary.

Claim 2, which is improperly dependent, is the broadest claim. Claim 1 is drawn to DNA comprising the entire gene cluster from *S. galilaeus* while Claim 2 is drawn to DNA comprising variants or parts of the entire gene cluster. Thus, the scope of Claim 2 must have a special technical feature that adds to the prior art to have unity of invention.

The Examiner notes that Claims 3-5 also do not properly depend from Claim 1 since only parts of the entire cluster are required in Claims 3-5. The Examiner suggests rewriting Claim 2 in independent form and rewriting Claims 3-5 to depend from only Claim 2.

### *Restriction*

3. Restriction is required under 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-5, drawn to a part of the full-length gene cluster for the anthracycline (aclacinomycin) biosynthetic pathway from *S. galilaeus*, and plasmids thereof.

Group II, claim(s) 9-15, drawn to methods of producing aclacinomycin using at least a part of the full-length gene cluster for the anthracycline (aclacinomycin) biosynthetic pathway from *S. galilaeus*.

4. The inventions listed as Groups I-II do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons.

The technical feature of Group I relies on the structural features of the portion of the *S. galilaeus* genome noted (see Claim 2). A portion of the gene cluster does not add to the prior art since a large portion of the gene cluster from *S. galilaeus* is disclosed in Fujii *et al.* (Anthracycline Biosynthesis in *Streptomyces galilaeus*. Chem. Rev. (1997) 97:2511-2523) (see Figure 7). Thus, the related products share the technical feature found in Group I and are grouped together. However, the processes of Group II do not share a special technical feature with Group I, which has no special technical feature, and are grouped separately.

### *Election*

5. A telephone call was made to Herbert Cantor on June 10, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 C.F.R. § 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(i).

***Conclusion***

6. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK  
June 11, 2003

